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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,399	11/08/2004	Mohammad Salman	RLL-244US	6687
<div>26815 7590 07/18/2007</div> <div>RANBAXY INC.</div> <div>600 COLLEGE ROAD EAST</div> <div>SUITE 2100</div> <div>PRINCETON, NJ 08540</div>				
			EXAMINER	
			CHUNG, SUSANNAH LEE	
			ART UNIT	PAPER NUMBER
			1626	
			MAIL DATE	DELIVERY MODE
			07/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,399	Applicant(s) SALMAN ET AL.	
	Examiner Susannah Chung	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 9-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 9 and 10-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 9, and 10-20 are currently pending in the instant application and are subject to the following new lack of unity requirement. The claims have not been numbered sequentially. Claims 2-8 have not been claimed and are not present in the application as filed. As of the date of this action no amendment to the claims have been filed.

Election/Restrictions

Restriction is required under 35 U.S.C. 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

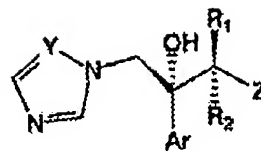
Claims 1, 9, and 10-20 are drawn to more than one inventive concept (as defined in PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

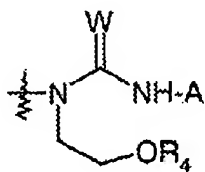
Due to the numerous and widely divergent variables in the compound of formula (I), for example Y, Ar, Z, W, A, B, m, R1, R2, R3, R4, R5, R6, etc., a precise listing of inventive groups cannot be made. The following groups are exemplary:

Art Unit: 1626

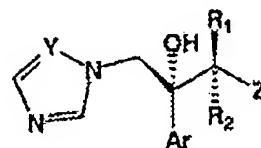


Group I: Claim 1 drawn to compound of formula (I), , wherein Ar

is a five membered heterocyclic ring containing one nitrogen heteroatom; R1 and R2 are

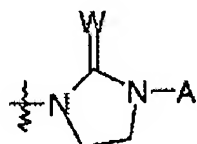


hydrogen; Y is CH; Z is ; W is oxygen; A is hydrogen; and R4 is hydrogen, as depicted in Claim 1, pages 17-21.

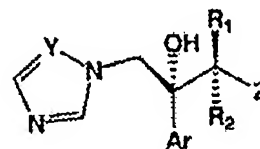


Group II: Claim 1 drawn to compound of formula (I), , wherein

Ar is a five membered heterocyclic ring containing one nitrogen heteroatom; R1 and R2 are



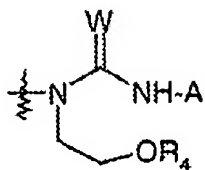
hydrogen; Y is CH; Z is ; W is oxygen; and A is hydrogen, as depicted in Claim 1, pages 17-21.



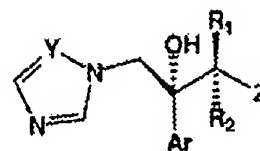
Group III: Claim 1 drawn to compound of formula (I), , wherein

Ar is a six membered heterocyclic ring containing one nitrogen heteroatom; R1 and R2 are

Art Unit: 1626

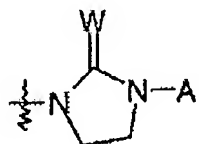


hydrogen; Y is CH; Z is ; W is oxygen; A is hydrogen; and R4 is hydrogen, as depicted in Claim 1, pages 17-21.

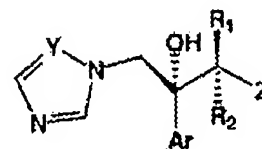


Group IV: Claim 1 drawn to compound of formula (I), , wherein

Ar is a six membered heterocyclic ring containing one nitrogen heteroatom; R1 and R2 are

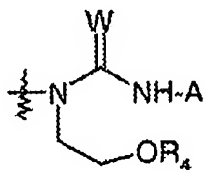


hydrogen; Y is CH; Z is ; W is oxygen; and A is hydrogen, as depicted in Claim 1, pages 17-21.



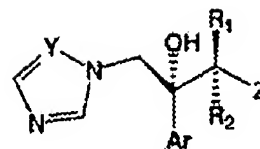
Group V: Claim 1 drawn to compound of formula (I), , wherein

Ar is a seven membered heterocyclic ring containing one nitrogen heteroatom; R1 and R2 are



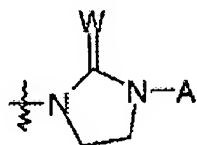
hydrogen; Y is CH; Z is ; W is oxygen; A is hydrogen; and R4 is hydrogen, as depicted in Claim 1, pages 17-21.

Art Unit: 1626

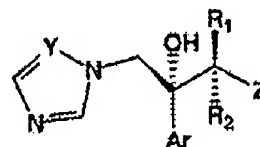


Group VI: Claim 1 drawn to compound of formula (I), , wherein

Ar is a seven membered heterocyclic ring containing one nitrogen heteroatom; R1 and R2 are

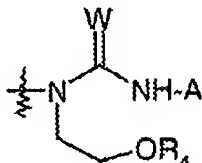


hydrogen; Y is CH; Z is ; W is oxygen; and A is hydrogen, as depicted in Claim 1, pages 17-21.

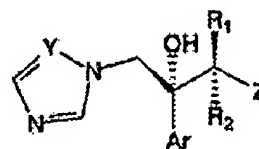


Group VII: Claim 1 drawn to compound of formula (I), , wherein

Ar is a five membered heterocyclic ring containing two nitrogen heteroatoms; R1 and R2 are

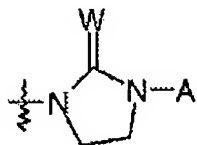


hydrogen; Y is CH; Z is ; W is oxygen; A is hydrogen; and R4 is hydrogen, as depicted in Claim 1, pages 17-21.



Group VIII: Claim 1 drawn to compound of formula (I), , wherein

Ar is a five membered heterocyclic ring containing two nitrogen heteroatoms; R1 and R2 are



hydrogen; Y is CH; Z is ; W is oxygen; and A is hydrogen, as depicted in Claim 1, pages 17-21.

Group IX: Claims 1 and 9 drawn to methods of using the compound of formula (I) to treat a fungal infection in a mammal comprising the step of administering to said mammal a therapeutically effective amount of the pharmaceutical composition of claim 7, as depicted in claims 1 and 9, pages 17-21.

Group X: Claims 10-20 drawn to a process for preparing a compound of Formula (II), and its pharmaceutically acceptable salts, as depicted in Claim 10, pages 22-24.

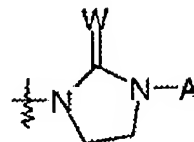
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Again, this list is not exhaustive as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention (a product or a method of use of said product) by identifying another specific embodiment, i.e. another value for Y, Ar, Z, W, A, B, m, R1, R2, R3, R4, R5, R6, etc..., not listed in the exemplary groups of the invention and examiner will endeavor to group the same.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a) the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The technical feature of the instant claim(s) is the heterocyclic ring connected to a linker -CH₂-C(OH)(Ar)-CH₂-Z group, which does not define a contribution over the prior art (as can be seen

Art Unit: 1626

by Itoh et al., U.S. Pat. Num. 6,034,248, formula (I) of Claim 1, Column 68), which corresponds



to applicants formula (I) wherein Y is nitrogen; and Z is . The variables on the compound vary extensively and when taken as a whole result in vastly different compounds.

Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

In addition, it should be noted that the claims are not in sequential order. Appropriate correction is required.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

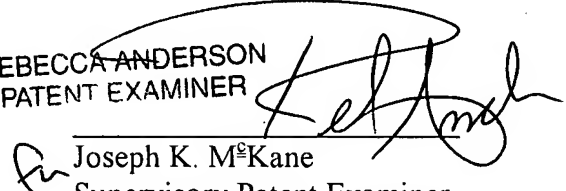
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

Art Unit: 1626

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLC

REBECCA ANDERSON
PATENT EXAMINER


Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

Date: 27 June 2007